

10/549409

JC20 Rec'd PCT/PTO 1 4 SEP 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION FOR U.S. LETTERS PATENT

Title:

HYDRAULIC DEVICE FOR THE INJECTION OF BONE CEMENT IN PERCUTANEOUS
VERTEBROPLASTY

Inventors:

Roque Humberto Ferreyro Irigoyen and Mario Marquez Miranda

Citizenship: Mexico

Citizenship: Mexico

Melissa W. Acosta, Ph.D.
FULBRIGHT & JAWORSKI L.L.P.
Fulbright Tower
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
(713) 651-5407

7/pets

10/549409

JC20 Rec'd PCT/PTO 14 SEP 2004
Docket No.: HO-P03225

HYDRAULIC DEVICE FOR INJECTION OF BONE CEMENT IN PERCUTANEOUS VERTEBROPLASTY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application the National Phase Application of International Application No. PCT/MX2003/000027 filed March 14, 2003.

TECHNICAL FIELD

[0002] This invention in a general way relates to the medical area in procedures where it is required to inject a dense or viscous fluid through a needle, in a particular way the viscous material is the polymethylmethacrylate. It is used in procedures like percutaneous vertebroplasty, kyphoplasty or other surgical events of the field. It has applications in other areas where it is required to apply at distance a dense and viscous liquid.

BACKGROUND OF THE INVENTION

[0003] Percutaneous vertebroplasty is a minimally invasive interventional radiological procedure that consists on injecting bone cement (Polymethylmethacrylate, PMMA) in the vertebral body, by trans-pedicular or oblique approach through a bone biopsy needle.

[0004] It was developed in France in 1984 for the treatment of aggressive or painful haemangiomas of vertebral bodies. For its analgesic effect, its use was quickly extended for the treatment of lytic metastatic lesions or myeloma and mainly in fractures or vertebral collapse due to osteoporosis. The procedure is indicated in those cases that are presented with severe and disabling pain that doesn't respond to conservative measures such as: corset use, analgesic and anti-inflammatory treatment or bed rest.

[0005] Most of the patients with this suffering are between the 6th and 8th decade of life. In this group of advanced age, the immobilization resulting from vertebral fractures has severe consequences in their general medical conditions, it predisposes them to cardiopulmonary, intestinal, circulatory complications, etc. Besides pain, the psychological effects can be devastating, it deteriorates the quality and reduces the expectation of life.

[0006] Vertebroplasty is a procedure that is carried out in hospital facilities that requires specialized medical personnel. It is performed in a hemodinamia room or cath lab, and it requires of the use of radiological equipment with high resolution fluoroscopy, mounted in a C arm. Currently, this injection is carried out in a manual and direct way and the operator is exposed to ionizing radiation every time that he/she practices a vertebroplasty. The injection of bone cement is made with fluoroscopic control, connecting an insulin syringe to the needle. This implies that the surgeon is in direct contact with the patient and therefore, overexposed to primary or secondary ionizing radiation during the lapse of the procedure of the vertebroplasty.

[0007] The primary radiation is the X ray beam coming from the X ray tube and received by the patient in a direct way, The secondary radiation it the one resulting on the deviation of the primary beam in the patient's body tissues and doesn't contribute to the formation of a diagnostic image, it is spread in all directions and it is the main source of exposure of medical personnel.

[0008] The insulin syringe is used since a small diameter barrel is required to have less resistance for the manual injection of high viscosity bone cement, each syringe is filled approximately in half or two thirds of its capacity to avoid bending or breaking the plunger when exercising the required injecting pressure that may be considerable. The volume needed to obtain the expected results varies from 3 ml up to 9 ml, therefore, 5 to 18 syringe exchanges are necessary, this favors the solidification of the polymethylmethacrylate and it can prevent to inject the wanted quantity.

[0009] If larger diameter syringes are used, the manual pressure is insufficient due to the density and viscosity of the bone cement; and becomes necessary the employment of a mechanical device to be able to exercise the required pressure. At the state of the art, there are commercially available devices such as pressure gun type or threaded plunger mechanisms connected directly to the needle that deposits the cement in the bone or through a high pressure short tube. The use of a long tube would have considerable resistance to the flow of the cement, favoring its solidification.

[0010] In most of these devices the syringe is not interchangeable, it is loaded with the total volume to inject and therefore, are of larger diameter and the increased resistance to the flow of the cement becomes worse with time due to solidification of cement.

[0011] On the other hand, the conventional hypodermic syringes are not designed for high pressure injection, the plunger and the fingers supporting wings bend easily.

[0012] The devices of the previous technique solve only the mechanical problem of injecting the dense and viscous cement through the needle but they are focused on exercising the necessary pressure directly on the patient or at a very short distance of the radiation source. They don't allow the operator to maintain an appropriate distance to reduced exposure to secondary radiation at acceptable levels according with the international radiological protection norms.

[0013] On the other hand, some mechanical devices do not allow control or manual sensibility of the exercised pressure and speed of the injection of the cement, important factors in the prevention of undesirable leaks and complications. Some devices that apply cement in the current state of the art are for example:

[0014] The patent application of the United States of America No. 2003/0018339, for Higuera et al, published January 23th of 2003, it discloses an application device for the controlled injection of bone cement, mounted in a syringe loaded with the cement, as a cartridge, which is discharged by a threaded metallic plunger placed in the other end of the device, it is useful for controlling the pressure exercised on the plunger of the syringe but it is a short device in which the operator is near the patient; It also contains the total load of cement.

[0015] On the other hand, due to the viscosity of the cement and quantity keeps certain dynamic memory that doesn't allow sudden interruption of the injection.

[0016] The patent application of the United States of America No. 2002/0156483, for Voellmicke et al, published October 24th of 2002, discloses a vertebroplasty device and bone cement, it contains two compartments, one for mixture of the cement and the other for storage and injection into the bone. This dual camera device for blending and injection, consists of a lodging camera with a plunger moving in an axial way, the cameras are in communication by a check valve that only allows the passage of the cement in one direction. An extra force can be exercise on the plunger by means of a lever that increases the mechanical force and therefore the pressure in the injection camera. This is a device in which it is necessary to work the piston of the blending camera and the piston of the injection camera to empty one and fill the other one

alternatively. It is a short device, it is necessary to be near the patient and doesn't reduce the exposure to secondary ionizing radiation.

[0017] The patent application of the United States of America No. 2002/0099384, for Scribner et al, published July 25th of 2002, discloses a system and method to treat vertebral bodies. It is a special syringe with two concentric plungers. The first camera that has a first transverse section and a second smaller camera than the first one. Both cameras communicate to each other. The first camera includes a gate to receive the material inside the filling instrument, the second camera includes a gate to discharge the contained material. A first plunger suited to pass through the first camera and displace the material. A second plunger to pass through the interior of the first plunger's concentric hole and reach the interior of the second camera to displace the material through the exit in the second camera to inject into the needle toward the interior of the vertebral body. Although this device provides control in the injection of the bone cement, the operator is too near the patient.

[0018] In general the injection devices have a bolster that impels the viscous fluid by means of a manual trigger moved by a screw mechanism (inclined plane), there are others that have a gun like body such as the device of the Patent Application of the United States of America. 2002/0049448, for Sand et al, published April 25th, 2002, It has a tubular body that stores a viscous flowing material (bone cement), it is a longitudinal body with a providing end and a driving end, a plunger housed inside the tubular body that displaces the flowing material along the longitudinal axis of the tubular body, the driving mechanism has a handle like a gun to hold with a hand, while injecting with the other hand by means of the plunger that advances due the pressure exerted by a threaded mechanism. These mechanisms with big deposits have the inconvenience that the cement can end up solidifying in the conduit at the time of application and impede to apply the total amount of cement inside the affected vertebral body. On the other hand, with the excess of pressure generated by these devices, the cement could leak outside of the vertebral body, since the fluid (PMMA), for its viscosity, possesses a remaining flowing memory that may be difficult to control.

[0019] The Patent of the United States of America Not. 6,348,055, for Preissman, published February 19th of 2002, protects a bone cement applying device with screw mechanism in which the preparation of the total volume of cement is made, this mechanism has an intermediate stabilizer that avoids the turns of the whole device during the application of

pressure to the fluid. The stabilizer is a lever perpendicular to the screw body that can be sustain with a hand, while with the other hand exercises the pressure to inject the cement inside the vertebral body. This device is also operated very near the patient and therefore, the operator is exposed to secondary ionizing radiation. Another inconvenience is that if the cement solidifies in the system and has not reached the vertebral body in the proper amount, it is necessary to make another preparation previous placement of another needle in a different and appropriate position for the new requirement.

[0020] The Patent Application of the United States of America No. 2002/0010431, for Dixon et al, published January 24th, 2002, discloses a screw device for high pressure with a threaded axis that impels a plunger inside a camera full with viscous bone cement. This device has the inconvenience that one doesn't have manual sensitivity and control of the pressure exercised, it is not easy to exchange the syringes with the bone cement. As a matter of fact, it is the only syringe of the cartridge.

BRIEF SUMMARY OF THE INVENTION

[0021] Among the several objects of the present invention, a better control of the pressure in the placement of bone cement or other viscous materials in the bone is provided. The invention facilitates the injection of viscous filler in trabecular bone or a cavity formed in the vertebral body.

[0022] Another object of the present invention it is to provide a hydraulic device to treat vertebral fractures and reduce the pain, stabilize the vertebral body, to obtain higher resistance to compression, avoid further collapse and at the same time, to allow early mobilization of the patients and improve their quality of life.

[0023] It is still another object of the present invention, to provide a device for the injection of viscous material in the vertebral body that allows the operator to keep and appropriate distance (1.0 m to 1.5 m) in order to reduce exposure to ionizing radiation at acceptable levels within the international norms.

[0024] It is also another object of the present invention, to provide a hydraulic press like device using syringes of unequal caliber (3 and 10 ml) to exercise hydraulic pressure at

distance transmitted from a proximal, manual syringe of smaller caliber, through the polyethylene tube until the distal or injecting syringe.

[0025] It is another object of the present invention to provide a cylinder of pressure with mechanical advantage complementary to an hydraulic system of syringes for injection at distance of polymethylmethacrylate suspension in the cancellous bone of a vertebral body. This way, the overexposure of the operator to ionizing radiation is reduced.

[0026] It is still another object of the present invention to provide a hollow cylinder or body of pressure in the shape of an inverted syringe to form a hydraulic device that allows manual control on the volume and velocity of injection polymethylmethacrylate (PMMA) and also immediate interruption of the pressure applied on the fluid.

[0027] It is still an object of the present invention, to provide a device that prevents the movements or abnormal displacements of the needle during the injection and syringes exchange (1 or 2 exchanges may be necessary), it reduces time loss and allows to maintain the bone cement loaded syringes in a recipient or cold atmosphere to slow time of solidification.

[0028] It is another object of the present invention, to provide a device that uses syringes from 3 to 5 ml that require smaller injection pressure, and can be exchanged easily with a single 90° rotation movement, Hub Lock type.

[0029] It is still an object of the present invention, to provide a device for injection of viscous material that can be manufactured of plastic, aluminum or any other disposable light-weighted material for single use or suitable for re-sterilization, sturdy enough to support the pressure of injection..

[0030] It is another object of the present invention to provide a flexible hydraulic, light-weighted device that prevents the movements or unwanted displacements of the needle during the injection.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] The figure 1, represents the connection outline of the novel hydraulic press like device for injection at distance, of the present invention.

[0032] The figure 2, represents an injection device with a screw type threaded plunger of the previous technique.

[0033] The figure 3, represents a device of injection of the previous technique, which has a recipient to make the mixture, another to exercise the injecting pressure. each recipient contains a check valve in their exit holes to avoid re-flow

[0034] The figure 4, represents a device of injection of the previous technique, which contains a larger capacity syringe in which the total amount of bone cement mixture is placed to inject, impelled by a threaded plunger.

[0035] The figure 5 represents the device object of the present invention corresponding to the transverse view of the piston together with the rubber cap.

[0036] The figure 6 represents the smaller, manual syringe for control of the device with the plunger and rubber cap.

[0037] The figure 7, it represents the syringe of force, the conduit (7) that transmits the pressure to the larger diameter device (B) .and the way to place the plunger (A) of the injecting syringe that contains the material and the injection needle.

[0038] The figure 8, represents a hydraulic press, theoretical basic principles of the present invention.

[0039] The figure 9, represents the pressure transmitted in the tube and the exit force generated, which pushes the plunger that injects the material through the needle.

DETAILED DESCRIPTION OF THE INVENTION

[0040] The present describes a new device and method to treat affections of the bones, specifically, in the treatment of osteoporotic or fractured vertebral bodies.

[0041] These bone structures have different pathological states of diverse ethiology (trauma, osteoporosis, primary bone tumors or metastasys, etc.). An alternative of treatment to stabilize and to consolidate this structures consists on the injection of a bio-materials such polymethylmethacrylate in the interior of the vertebral body for healing purpose.

[0042] The injection of biomaterials such as bone cement is carried out by means of a hydraulic device exerting pressure on small caliber conventional syringes connected directly to the needle; since the cement has the property of becoming hard quickly.

[0043] The theoretical basic principle for the operation of the device of the present invention consists on the amplification of the hydraulic pressure generated at distance and transmitted by the hydraulic tube.

[0044] In reference to the figure 8, the most frequent application to the Law of Pascal is the hydraulic press that consists of two asymmetric columns of liquid. This principle is applied in mechanical devices of engineering areas, this columns are different in the size or diameter of the transverse section. In accordance with the Law of Pascal, a pressure applied in one of the columns is transmitted entirely and in all directions. Therefore, if a force F_1 is applied on the area piston A_1 , it will cause an exit force F_0 that acts on an area A_0 of the piston. This way, the entrance pressure is the same to the exit pressure, that is to say:

$$F_1/A_1 = F_0/A_0$$

[0045] The ideal mechanical advantage of the device is similar to the relationship of the exit force with regard to the entrance force.

$$VM = F_0/F_1 = A_0/A_1$$

[0046] Where a small entrance force can be multiplied (A_0/A_1 times) to produce a larger exit force (F_0), using an exit piston with a larger area than that of the entrance piston. The exit force will be given by:

$$F_0 = F_1 A_0/A_1$$

[0047] If friction is disregarded, in an ideal situation the entrance work should be the same to the exit work. Therefore, if the force F_1 travels a distance S_1 while the exit force F_0 travels a distance S_0 , there is equality.

$$F_1 S_1 = F_0 S_0$$

[0048] The mechanical advantage can be expressed in terms of the distances traveled by the pistons:

$$VM = F_0/F_1 = S_1/S_0$$

[0049] It is observed that the mechanical advantage is obtained at expenses of the distance that the entrance piston travels.

[0050] In reference to the figure 9 that describes the body (B) and area (95) of the piston of larger area of the present invention, it is also represented the entrance of the pressure P_1 that is transmitted through the incompressible fluid, either water or oil, content in the flexible tube (not shown) that generates an exit force F_0 . The attachment (2) for the lateral wings of the injecting syringe that contains the bone cement acts as coupler to the device, the wings enter tightly in the internal peripheral groove (70) diametrically opposed inside the bolster(header) of the body of the device object of the present invention, with a turn of 90° either clockwise or counterclockwise. The plunger of the syringe enters in the longitudinal central space (95) of the body (B).

[0051] Returning to the figure 1, the hydraulic device consists of four main parts arranged one after another in such a way that allows to inject at distance and in a controlled way (regarding the pressure) viscous materials such as polymethylmethacrylate used in percutaneous vertebroplasty for the reestablishment (without surgery) of patient with osteoporotic fractures.

[0052] The device here described is designed to inject at distance a polymethylmethacrylate suspension with viscous consistency, directly in the cancellous bone of the vertebral bodies by means of a syringe loaded with the bone cement attached to a bone biopsy needle. The device consists of four main parts, "injecting syringe" in vicinity to the patient, "pressure" exerting body, "hydraulic transmission tube" and "manual syringe". In this, the fingers of the operator exercise the controlled force. This control is carried out by the operator's tact sensitivity. This device conforms a hydraulic system for polymethylmethacrylate injection at a variable distance from the patient (usually 1 m to 1.5 m).

[0053] The injection part is a commercially available, disposable 3 ml. hypodermic syringe (a) that is placed next to the patient, loaded with the bone cement that consists of a plunger (11) that pushes the material (CO) to be injected in the vertebral body through a bone needle (CA), (not shown). This syringe couples tightly in a revolved way, by means of the opposed wings of support (b), in a peripheral groove in the internal face of the bolster (2) of the body of pressure, it is coupled by means of the opposed wings (b) used as support for the fingers in an act of usual injection, these wings (b) are placed in the entrance guide and rotated, either clockwise or counterclockwise an angle of 90° to stay in tightly fixed to avoid inadvertent detachment and loss of the pressure. The injection needle is coupled rotating the threaded distal end (CA) in the usual way of common plastic syringes in order to avoid

spillage of the material to be injected due to the high pressure exercised on the plunger (c) and its end (3). For exchange, the empty syringe is detached from the needle, and then from the pressure device by means of a 90° rotation, discarded (2) and replaced with another loaded syringe prepared in advance and stored in a cold environment to delay curing and hardening of the cement. The syringe (a) is of 3 or 5 ml capacity.

[0054] The part of pressure, consists of distal inverted syringe body (1) of larger diameter than the syringe at the proximal end of the complete device, It has a bolster (2) open to the atmospheric pressure that contains an internal peripheral groove where the opposed supporting wings of the injecting disposable hypodermic syringe are coupled (b) with a turn of 90°. Its interior is open to the atmospheric pressure and receives the plunger of the injecting syringe (c) in a extended position to make contact with the rigid surface of the piston (3), The piston moves tightly with respect of the internal wall of the device (1) by means of a rubber cap (4), to maintain a closed hydraulic space (5) The distal pressure is transmitted to the piston through the opening or mouthpiece (6) connected to the flexible tube of polyethylene or similar material (7) by means of the hydraulic fluid (10). The rigid surface of the piston (3) exercises pressure (which has been increased by the device) on the plunger(11) of the injecting syringe. The body (1) is manufactured of transparent plastic, aluminum or any other suitable light-weighted and rigid material. Other characteristics of the body will be described (1) with more detail in the figures 5, 7 and 9.

[0055] The hydraulic tube for pressure transmission (the Pascal's Principle), is a tube or flexible hose of polyethylene or similar material of little weight, with appropriate diameter to couple in the distant and proximal ends of the syringes, the longitude is variable, most commonly of 1.0 m to 1.50 m, it is resistant to the internal pressure. The tube is loaded of water, oil or other non-compress fluid (10) to integrate together with the manual proximal syringe and the body of pressure closed hydraulic system.

[0056] The manual syringe (8), has a smaller diameter than the body of pressure (1) in a 2/1, 3/1 or 4/1 ratio that may vary according to the necessity of each case. According to the hydraulic press described in the figure 8, the longitude of the manual syringe should be larger than that of the body of pressure (1) with the purpose of containing enough volume to displace the piston the distance required to impel the plunger of the injecting syringe. this way, the quantity required of bone cement is deposited in the vertebral body .

[0057] The device works in the following way: a manual force is exercised on the plunger (9) of the manual syringe (8) in its extended position, the force exercises a pressure that is transmitted through the incompressible fluid (10) content in the flexible tube and in the camera (5) of the body of pressure (1). This pressure exercises an increased force on the plunger of the injecting syringe, due to the mechanical advantage of the relationship of areas or displacements formerly described. The plunger of the injecting syringe in turn, exert a force that impels (to) the material or cement to be injected in the patient's vertebral body through the bone biopsy needle. Once the total amount or content of the injecting syringe has been delivered, the plunger of the manual syringe is retracted to generate space inside the body of pressure (1) by retracting the piston to replace the emptied syringe with a loaded new syringe to continue the injection. Up to 10 ml. of bone cement is required to achieve an suitable filling of the fractured vertebral body, therefore, 3 to 4 syringe exchanges may be necessary.

[0058] The bone needle stays in place during the procedure that is to say, the movements or abnormal displacements of the needle during the injection are avoided, situation that implies several advantages: For the patient, since additional punctures are less frequent and for the operator with less problems of solidification of the cement.

[0059] Another advantage of the device is that the transmission of the pressure is immediate, that is to say, doesn't have a dynamic memory by effects of the increasing viscosity due to the solidification in the injection conduit specially with prolonged injections, prone to happen in the injecting devices of the previous technique that are loaded with the complete volume of cement to be placed. On the other hand, the threaded plunger doesn't allow tact sensibility regarding the exercised pressure and therefore favors unwanted leakage of the bone cement due to the dynamic memory of the material.

[0060] To this respect we have devices of the previous technique such as the (20) figure 2 that consists of a threaded plunger (23) that impels the contained cement in the camera (24) and a refilling deposit (22) that in turn feeds the camera by means of a plunger (21); A handle (25) that serves for support to the other hand of the operator to facilitate exercise the intense force so that the cement flows in a short tube (26) and it is injected through the needle (27).

[0061] The device (30) of the previous technique of the figure 3 contains two cameras (35) (32) connected by a valve check in the conduit (37). The bone cement is mixed In the camera (35) and impelled to the injection camera (32) by means of a plunger(36), once in the injection camera the cement is impelled by the piston (38) of a plunger (34) moved by a lever that provides the required force (33), forcing the cement through the opening (31) that in turn contains a valve check that closes in the recharge operation.

[0062] The figure 4 illustrate another device (40) of the previous technique for injection of polymethylmethacrylate. In this one the threaded plunger (41) has a crank (42) in the end to facilitate impel the total content of the syringe (45), and supporting elements (43) (44) for the other hand of the operator in the action of injection of the bone cement.

[0063] The figure 5, represents a cut profile and front view the body of pressure (50) that shows the groove of the bolster (2) where the injecting syringe that contains the bone cement is secured. Also presents the front view and profile of the piston (51) and the rubber cap (52) that avoids spillage of the hydraulic fluid in the action of transmission of the pressure. With this body of pressure, object of the present invention, is possible to transmit the pressure at distance and therefore reduces exposure of the operator to secondary ionizing radiation coming from the patient at the time of placement of the bone cement. This body of pressure complies with the characteristic of being light-weighted, may be disposable or reusable, manufactured of plastic, aluminum or other suitable material able to support sterilization.

[0064] The figure 6, represents frontal and lateral views of the manual or impulsion syringe (60), and plunger (61) where the rubber cap is placed (62) to avoid leakage of the hydraulic fluid. The bone cement should be kept in a cold environment before it is applied so it is maintain fluid to avoid solidification in the needle.

[0065] In the figure 7, the transverse cut of the cylindrical hollow body of pressure is described (B) that houses the plunger (A) of the injecting syringe secured in the peripheral groove (70) of this body of pressure, it is connected to the flexible tube (7) that transmits the hydraulic pressure (10), exercised from the manual or impulsion syringe (C) by means of its plunger (9). Here is illustrated the way the injecting syringe is attached to the body of pressure, Once introduced the plunger (A) in the opening of the body of pressure (B) the syringe is turned

90° in such a way that the body of the syringe is tightly secured to proceed with the injection of the bone cement.

[0066] The use of small diameter syringes in the application of the cement has the advantage of less resistance to flow, so a more viscous cement can be injected to reduce the possibilities of leakage from the vertebral body.

[0067] The experts in the technique expect other embodiments of the invention might exist, that is to say, embodiments of instruments built according to the teachings of the present invention. Because many of the characteristics of the embodiments are similar to those previously described. Peculiar embodiments of the invention have been illustrated and described in those that it will be obvious for those experts in the technique that several modifications or changes can be made without leaving the reach of the present invention. The above-mentioned tries to cover with the added claims so that the changes and modifications fall inside the reach of the present invention.